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TREATMENT CENTER, INC.,  
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CORPORATION, ELLIOT B. LANDER, M.D.  
and MARK BERMAN, M.D.

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
EASTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

CALIFORNIA STEM CELL  
TREATMENT CENTER, INC., a  
California corporation, CELL SURGICAL  
NETWORK CORPORATION, a  
California corporation, and ELLIOT B.  
LANDER, M.D., MARK BERMAN,  
M.D., individuals,

Defendants.

CASE NO. 5:18-CV-01005-JGB-KK

Hon. Jesus G. Bernal  
Riverside, Courtroom 1

**DEFENDANTS'  
SUPPLEMENTAL  
BRIEF RE: PROPER  
INTERPRETATION OF  
21 C.F.R. § 1271.3(D)**

Action Filed: May 9, 2018  
Trial Date: May 4, 2021  
Closing Arguments: August 20, 2021

1 Defendants California Stem Cell Treatment Center, Cell Surgical Network  
2 Corporation, Elliot Lander, M.D., and Mark Berman, M.D., hereby submit this  
3 supplemental brief regarding the proper interpretation of 21 C.F.R. § 1271.3(d)  
4 (“Section 1271.3(d)”) and how that intersects with the same surgical procedure  
5 exception (“SSP Exception”) under 21 C.F.R. § 1271.15, per this Court’s directive  
6 at the conclusion of closing arguments on August 20, 2021.

7 The SSP Exception exempts from FDA oversight any “establishment that  
8 removes HCT/Ps from an individual and implants such HCT/Ps into the same  
9 individual during the same surgical procedure.” 21 C.F.R. § 1271.15. The SSP  
10 Exception therefore hinges largely on the definition of “HCT/Ps” under Section  
11 1271.3(d) and how to interpret “such HCT/Ps” relative to the first reference to  
12 “HCT/Ps” in the SSP Exception.

13 “HCT/Ps” is an acronym for “[h]uman cells, tissues, or cellular or tissue-  
14 based products,” and HCT/Ps are defined in Section 1271.3(d) as “articles  
15 containing or consisting of human cells or tissues that are intended for  
16 implantation, transplantation, infusion, or transfer into a human recipient.”  
17 21 C.F.R. § 1271.3(d).

18 Settled canons of statutory construction guide the interpretation of these  
19 provisions. In that respect, “[i]t is a cardinal principle of statutory construction that  
20 a statute ought, upon the whole, to be so construed that, if it can be prevented, no  
21 clause, sentence, or word shall be superfluous, void, or insignificant.” *TRW Inc. v.*  
22 *Andrews*, 534 U.S. 19, 31 (2001). As the Government acknowledged at summary  
23 judgment, a “[c]onstruction which gives effect to *all of the words* of a statute or  
24 regulation is preferred over an interpretation which renders some of the statute or  
25 regulation ineffective.” *First Charter Financial Corp. v. United States*, 669 F.2d  
26 1342, 1350 (9th Cir. 1982) (emphasis added, citation omitted); *see also United*  
27 *States v. Canals-Jimenez*, 943 F.2d 1284, 1287 (11th Cir. 1991) (“A basic premise  
28

1 of statutory construction is that a statute is to be interpreted so that no words shall  
2 be discarded as being meaningless, redundant, or mere surplusage.”).

3 • **A Plain Language Analysis of Section 1271.3(d)**

4 To obtain a construction of Section 1271.3 that gives effect to *all* the words  
5 in the definition, it is helpful to break that definition down into its parts. As noted,  
6 HCT/Ps are “articles containing or consisting of human cells or tissues that are  
7 intended for implantation, transplantation, infusion, or transfer into a human  
8 recipient.” 21 C.F.R. § 1271.3(d). The plain language of Section 1271.3(d) is not  
9 ambiguous. Taking each word in turn:

10 What are “articles”? “Articles” are not specifically defined by the FDCA,  
11 but common usage defines “articles” as “things . . . of a particular class” or  
12 “individual objects.” <https://www.merriam-webster.com/dictionary/articles>;  
13 <https://www.dictionary.com/browse/article>. Thus, HCT/Ps are “things.” There is  
14 no meaningful dispute about this.

15 What type of “articles” or “things” are HCT/Ps? Per Section 1271.3(d),  
16 HCT/Ps are things “containing or consisting of” “human cells or tissues” “that are  
17 intended for implantation, transplantation, infusion, or transfer into a human  
18 recipient.” These three quoted portions each warrant individual consideration.

19 Is there a distinction between “containing” and “consisting of”? Yes,  
20 as this Court noted and the Government agreed. (8/20/21 Tr. at 15:25-16:8.)  
21 *See Bailey v. United States*, 516 U.S. 137, 146 (1995) (“We assume that  
22 Congress used two terms because it intended each term to have a particular,  
23 nonsuperfluous meaning.”). “Containing” means “to have” or “to hold” or “to  
24 include.” <https://www.merriam-webster.com/dictionary/containing>;  
25 <https://www.dictionary.com/browse/containing>. “Consisting of” means “to be  
26 composed of or made up of.” <https://thelawdictionary.org/consisting/>.  
27 Black’s Law Dictionary further explains that “consisting of” is “not synonymous  
28 with ‘including;’ for the latter, when used in connection with a number of specified

1 objects, always implies that there may be others which are not mentioned.”  
2 <https://thelawdictionary.org/consisting/>. Giving effect to this plain language and  
3 the recognized distinction between the words used, when a “thing” is “containing”  
4 something or things, it also may contain or include other things. Where a “thing”  
5 is “consisting of” something or things, the thing is made up of only those things.  
6 Thus, the articles that constitute HCT/Ps under Section 1271.3(d) can include  
7 human cells or tissues among other things, or the articles can be made up of *only*  
8 human cells or tissues. Simplified down, the articles that constitute HCT/Ps *are*  
9 human cells or tissues—either in part or in whole.

10 Next, is there a distinction between “human cells” and “tissues”? Yes.  
11 That is evident by the disjunctive “or” language in Section 1271.3(d) and it is an  
12 undisputed fact in this case. Cells are the smallest and most basic functional  
13 structural units in the human body. Cells can only be removed from an individual  
14 along with larger systems, such as the tissues or organs that they comprise. (*See*  
15 *5/7/21 PM Tr. 19:9-12 (Yong); 5/11/21 AM Tr. 112:13-19 (Berman)*). Thus, even  
16 though cells cannot be removed without also removing the larger systems they  
17 comprise, the unambiguous language of Section 1271.3(d) contemplates that cells,  
18 distinct from their surrounding tissues, can be HCT/Ps.

19 Finally, are the human cells or tissues “intended for implantation”? This  
20 aspect of the definition is critical to understanding whether and what “human cells  
21 or tissues” are the HCT/Ps at issue. HCT/Ps do not encompass just *any* “article  
22 containing or consisting of human cells or tissues.” If the human cells or tissues  
23 are *not* “intended for implantation,” they are not HCT/Ps. If the human cells or  
24 tissues *are* “intended for implantation,” they are HCT/Ps.

25 Thus, HCT/Ps are not defined in any way by what or how any of the cells or  
26 tissues are removed. HCT/Ps are defined only by whether they are “human cells or  
27 tissues intended for implantation.” And this makes sense. As noted, it currently is  
28 not technologically possible to remove *only* cells and not the larger systems they

comprise, and it certainly was not possible to remove only cells when Section 1271.3(d) was promulgated. If HCT/P status depended on what was removed, inclusion of “cells” in the definition of HCT/Ps would be superfluous because cells cannot be removed without tissue. Similarly, the fact that tissues comprised of cells are removed does not render the tissues the HCT/Ps. Rather, HCT/P status depends on what “human cells or tissues”—it could be either or both—are “intended for implantation.” If the tissues removed from an individual are “intended for implantation,” those tissues are HCT/Ps under Section 1271.3(d). And if the tissues removed from an individual are not “intended for implantation,” like the adipose tissues at issue here, those tissues are not HCT/Ps. Likewise, if the cells isolated from removed tissues are the cells “intended for implantation,” like the SVF cells at issue here, those cells are HCT/Ps under Section 1271.3(d). (See 8/20/21 Tr. at 19:20-20:5.)

• **How Section 1271.3(d) Intersects With The SSP Exception**

Having simplified the meaning of HCT/Ps under Section 1271.3(d) down to “human cells or tissues intended for implantation,” the SSP Exception applies when an “establishment removes HCT/Ps [or human cells or tissues intended for implantation] from an individual and implants such HCT/Ps [or human cells or tissues intended for implantation] into the same individual during the same surgical procedure.” 21 C.F.R. § 1271.15.

With the plain language definition of HCT/Ps limited to the “human cells or tissues intended for implantation,” so long as the cells intended for implantation are removed from a patient and implanted back into the same patient in the same procedure, the SSP Exception applies.

That is precisely what the SVF Procedure does here. It removes adipose tissues from the patient; those adipose tissues are not intended for implantation and therefore are not the relevant HCT/Ps. The SVF Procedure then isolates from the removed adipose tissue the SVF cells that *are* intended for implantation; those

SVF cells therefore are the relevant HCT/Ps, i.e., the “remove[d] HCT/Ps” under the SSP Exception. The SVF Procedure then implants those SVF cells, i.e., “such HCT/Ps,” back into the same patient during the same procedure. Thus, the SSP Exception applies.

The Government has argued the SSP Exception does not apply to the SVF Procedure because the HCT/Ps that are implanted (undisputedly, the SVF cells) are not “such HCT/Ps” that are removed. But that argument reflects a misinterpretation of HCT/Ps under Section 1271.3(d). By focusing only on what is removed, i.e., the adipose tissues, to define the HCT/Ps, the Government ignores the plain language of Section 1271.3(d) that limits HCT/Ps to those “human cells or tissues *intended for implantation*.” The SVF Procedure does not ever consider the removed adipose tissues to be “intended for implantation.” The SVF Procedure only contemplates that the SVF cells that are isolated from the removed adipose tissues are the “cells” “intended for implantation.” Therefore, only the SVF cells are the relevant HCT/Ps for purposes of the SSP Exception.

Lastly, according to the evidence adduced at trial, the SVF cells that are removed from a patient are the very same SVF cells or “such HCT/Ps” that are implanted in the patient in the same surgical procedure. (*See* 5/12/21 AM Tr. 85:7-86:8; 89:21-91:1, 99:24-101:13 (Reid); 5/12/21 PM Tr. 85:12-18 (Lander)). Thus, the SSP Exception applies to the SVF Procedure.

Dated: August 27, 2021

Respectfully submitted,

JONES DAY

By: /s/ Celeste M. Brecht  
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